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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,619	08/06/2001	Richard Apodaca	ORT-1474	8473

27777 7590 05/22/2002

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EXAMINER

WRIGHT, SONYA N

ART UNIT PAPER NUMBER

1626

DATE MAILED: 05/22/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,619

Applicant(s)

APODACA ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 47, 51-55 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 59 is/are rejected.
- 7) ☐ Claim(s) 1-46, 48, 49 and 56-58 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-60 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group II, claims 1-60 drawn to compounds and methods of use wherein G or W are a directly linked piperazine and morpholine in Paper No. 5 is acknowledged.

The Examiner has considered Applicant's request that G or W is L2Q be included with Group II. However, G or W as L2Q will not be included with Group II because "Q" will introduce a plethora of heterocycles with various classifications. The inclusion of the heterocycles in Q will impose a burdensome search of many classes and subclasses on the Examiner. Additionally, claims 47 and 51-55 and 60 have been restricted out because these claims are drawn to a method of treatment comprising a combination of drugs in dosage, time, and site of administration, and examination of these claims requires a search in additional classes and subclasses.

Unpatentability of Group II does not necessarily imply unpatentability of Groups I and III. Merit examination must be performed individually. Were Applicant to argue that the Groups are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the Groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Were Applicant to argue that the Groups are not distinct, then there could be no patentability of all the claims over

US Patent 5,580,883, Goto et al. See Examples 69 and 70 in Goto et al..

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-51 and 56-59 drawn to compounds and methods of use wherein G and W are piperazine and morpholine and all other variables are as defined, has been examined.

The non-elected subject matter of claims 1-51 and 56-59 and claims 52-55 and 60 in their entirety have been withdrawn from consideration.

Claims 1-51 and 59-59 are objected to for containing non-elected subject matter. It is requested that Applicant limit the claims to the elected subject matter in order to overcome this objection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over CAPLUS AN 1996:754425, Goto et al. in view of Greene, "Protective Groups in Organic Synthesis".

Determination of the scope and content of the prior art (MPEP §2141.01)

Goto et al. disclose aminophenycypiperidines for use as nerve cell protectants. Greene discloses various nitrogen protecting groups, including acyl and benzyl.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Goto et al. and the instant claims is that Goto et al. disclose an acyl protecting group on the nitrogen of the piperidine ring, while the instant claims consist of a (phenyl)C1-6alkyl protecting group on the nitrogen of the piperidine ring.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to use the disclosure of Goto et al. to prepare the instant compounds because the substitution of a (phenyl)C1-6 nitrogen protecting group for an acyl nitrogen protecting group is an obvious variant. See Greene, page 219 #40 and #48, and page 220 #2.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For rejections under 35 U.S.C. 112, first paragraph, the

following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
 - 2) State of prior art.
 - 3) Level of ordinary skill in the art.
 - 4) Level of predictability in the art.
 - 5) Amount of direction and guidance provided by the inventor.
 - 6) Existence of working examples.
 - 7) Breadth of claims.
 - 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.
- Claim 59 is directed to "the prevention of upper airway allergic response, nasal congestion, allergic rhinitis." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It has not been shown in the specification that the testing protocol used is accepted in the art as being predictive of the alleged utility. There are a vast number of of upper airway allergic response, nasal congestion, allergic rhinitis related disorders and applicant does not give support for "preventing" all forms of these disorders. The art pertaining to of upper airway allergic response, nasal congestion, allergic rhinitis remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature

of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that applicants delete "or prevention" from claim 59 in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

Claim 50 is drawn to a "method of treating a subject having a disease or condition modulated by histamine H3 receptor activity". The term "modulate" renders the claim indefinite. "Modulate" means that a histamine H3 receptor can both inhibit and cause a disease or condition. It is unclear whether Applicant claims that the role of histamine H3 is to inhibit or to cause a disease or condition. Appropriate correction is required.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 51 recites the broad

recitation "mild cognitive impairment", and the claim also recites "(predementia)" which is the narrower statement of the range/limitation.

In order to overcome this rejection, it is suggested that Applicant delete "(predementia)" from claim 51 and add a claim which depends on claim 51, wherein the disease or condition is predementia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

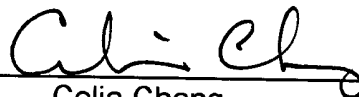
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not

communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

A handwritten signature in cursive script, appearing to read 'Celia Chang', is written over a horizontal line.

Celia Chang

Primary Examiner

Group 1600

Sonya Wright

May 16, 2002